FEB 27 2009

EXHIBIT #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K090362

1. **Manufacturer and Sponsor Contact Information**

Voguestrap
31-00 47th Ave
Long Island City, NY 11101
Phone: 718-706-8700 x 127
Fax: 718-706-8978
Contact Name: Sy Greenwald

Date Summary Prepared: December 29, 2008

2. **Name of the Device:** Voguestrap Contact Lens Cases, Models: IMAG, IPOD, EZ-Find, ISLIDE
   Classification: Class II, 21 CFR 886.5928
   Product Code: LRX

3. **Common or Usual Name:** Contact Lens Case

4. **Predicate Device Information:**

Bonasse Contact Lens case K991206

5. **Device Description:**

The Voguestrap Contact Lens Cases are plastic cases designed such that they are flat storage cases that have either screw top caps or flip top caps. The cases are labeled with an 'R' or 'L' to distinguish right and left lenses. The cases also come in different colors. The screw top model may also have a magnifying glass.

6. **Intended Use:**

The Voguestrap Contact Lens Cases are intended for the storage of soft (hydrophilic), rigid gas permeable (RGP), or hard contact lenses during chemical disinfection. For use in storage during chemical disinfection only. Not to be used with hydrogen peroxide disinfection systems.

7. **Comparison to Predicate Devices:**

The Voguestrap device has the same intended use, similar materials and design as the predicate device.

8. **Discussion of Non-Clinical Tests Performed in Determination of Substantial Equivalence:**

Biocompatibility testing performed by third party laboratory demonstrated the materials are safe for use in contact lens storage and disinfection.

9. **Conclusions:**

The Voguestrap Contact Lens Cases are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Underwriters Laboratories, Inc
c/o Mr. Casey Conry
Sr. Project Engineer
1285 Walt Whitman Rd.
Melville, NY 11747

FEB 27 2009

Re: K090362
Trade/Device Name: Voguestrap Contact Lens Cases, Models: IMAG, IPOD, EZ-Find, ISLIDE
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LRX
Dated: February 12, 2009
Received: February 13, 2009

Dear Mr. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit 3

Indications for Use

510(k) Number (if known): K090362

Device Name: Voguestrap Contact Lens Cases, Models: IMAG, IPOD, EZ-Find, ISLIDE

Indications For Use:

The Voguestrap Contact Lens Cases are intended for the storage of soft (hydrophilic), rigid gas permeable (RGP), or hard contact lenses during chemical disinfection. For use in storage during chemical disinfection only. Not to be used with hydrogen peroxide disinfection systems.

Prescription Use _____ **OR** **Over-The Counter Use** X
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K090362